



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/788,606

02/27/2004

Mary E. Brunkow

31173/40002

9642

4743

7590

11/23/2009

MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 SEARS TOWER
CHICAGO, IL 60606-6357

EXAMINER

XIE, XIAOZHEN

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/788,606	Applicant(s) BRUNKOW ET AL.	
	Examiner XIAOZHEN XIE	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89 and 91-109 is/are pending in the application.
- 4a) Of the above claim(s) 97-100 and 107-109 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 89 and 91-96 is/are allowed.
- 6) ☒ Claim(s) 101-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090320</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The Information Disclosure Statement (IDS) filed 20 March 2009 has been entered. Applicant's amendment of the claims filed on 31 July 2009 has been entered. Applicant's remarks submitted on 31 July 2009 are acknowledged.

Claims 1-88 and 90 are cancelled. Claims 89 and 91-109 are pending. Claims 97-100 and 107-109 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 89, 91-96 and 101-106 are under examination.

Claim Rejections Withdrawn

The rejection of claim 101 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in response to Applicant's amendment of the claim to recite wherein the polypeptide is isolated.

The rejection of claims 89, 91-96 and 101-106 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's amendment of the claims to limit that the polypeptides to which the antibody or antibody fragment thereof specifically binds are at least 90% identical to the secreted protein encoded by SEQ ID NO: 1, 5, 9, 11, 13 or 15. The instant specification has provided representative number of species for the genus of the polypeptides that meet the percentage of homology, as well as the structural and functional limitations (i.e., retaining a cysteine backbone and the ability to decrease bone mineral content).

The rejection of claims 89, 91-96 and 102 under 35 U.S.C. 102(a) as being anticipated by Valenzuela et al (WO 98/49296), is withdrawn in response to Applicant's amendment of the claims to refer 90% identity to the secreted protein encoded by the SEQ IDs (i.e., *"an isolated antibody or antigen binding fragment thereof which specifically binds to a polypeptide at least 90% identical to the secreted protein encoded by a polynucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 5, 9, 11, 13 and 15).*

The rejection of claims 101 and 103-106 under 35 U.S.C. 102(e) as being anticipated by Rueger et al. (U. S. Patent No: 6,949,505 B1), is withdrawn in response to Applicant's amendment of the claims to limit the antibody or an antibody fragment thereof (instead of the polypeptide) that binds to the secreted protein encoded by SEQ ID NO: 1.

Claim Rejections Maintained

Double Patenting

Claims 89 and 91-96 remain rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-8 of U. S. Patent No: 6,803,453 for reasons set forth in the previous office actions.

Applicant submitted a Terminal Disclaimer on 21 November 2008 to obviate the rejection. However, the Terminal Disclaimer is defective, specifically, the U. S. Patent No: 6,804,453 is incorrect, and it should be "6,803,453".

Claim Rejections - 35 USC § 112

Art Unit: 1646

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 101-106 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

1) an isolated antibody or antigen binding fragment thereof which specifically binds to a polypeptide at least 90% identical to the secreted protein encoded by a polynucleotide sequence selected from the group consisting of SEQ ID NOs: 1, 5, 9, 11, 13 and 15, wherein said polypeptide retains a cysteine backbone comprising eight cysteines and retains the ability to decrease bone mineral content; or

a conjugate molecule comprising the antibody or antigen binding fragment thereof and an effector or receptor moiety; and

2) an isolated antibody or antibody fragment thereof that binds to the secreted protein encoded by SEQ ID NO: 1, wherein the antibody or antibody fragment thereof binds said protein with an affinity of $K_a \geq 10^7 M^{-1}$; or

a conjugate molecule comprising the antibody or antibody fragment thereof and an effector or receptor moiety;

does not reasonably provide enablement for a genus of polypeptides comprising the antibody or antibody fragment thereof. The reasons of this rejection have been set forth in the previous office action (mailed 3/31/2009) and the following.

Claims 101-106 use the phrase "a polypeptide comprising an antibody, or an antibody fragment thereof". As stated previously, a polypeptide is a continuous chain of

Art Unit: 1646

amino acids joined by peptide bonds, whereas an antibody contains four polypeptides, 2 heavy chains and 2 light chains joined by disulfide bonds. The specification fails to provide guidance how to make “a polypeptide (a chain of amino acids joined by peptide bonds) comprising an antibody, or an antibody fragment thereof (which is a dimer or tetramer of polypeptide)”. While antibody molecules are frequently linked to an auxiliary moiety, such as a toxin, label, enzyme, etc., and the specification also discloses conjugating the antibody or antigen binding fragment thereof to an effector or receptor molecule, including non-peptide moieties (e.g., antineoplastic agents, toxins, polymers, radionucleotides, and compounds which may be detected by NMR or ESR spectroscopy), and peptide moieties (e.g., enzymes and fragments thereof that facilitate detection). However, the claim language reads on a very broad genus of molecules, for example, it reads on an antibody or antigen binding fragment thereof has a linear polypeptide structure; and it also reads on the antibody or antigen binding fragment thereof linked to any protein/peptide. The specification does not provide sufficient guidance for making and using such a broad genus of polypeptides. The state of the prior art also fails to provide compensatory teachings. Without sufficient guidance from the specification, one of ordinary skill in the art would not know how to make and use the broadly claimed molecules. Accordingly, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention commensurate in scope with these claims, and the enablement requirement sets forth in the 35 U.S.C. 112, first paragraph, is not met.

Conclusion

CLAIMS 89 AND 91-96 ARE ALLOWABLE.

CLAIMS 101-106 ARE REJECTED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/788,606
Art Unit: 1646

Page 7

Xiaozhen Xie, Ph.D.
November 16, 2009

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646